

**UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION**

**AXCESS GLOBAL SCIENCES, LLC,
PRUVIT VENTURES, INC., and UNIVERSITY
OF SOUTH FLORIDA RESEARCH
FOUNDATION, INC.**

Plaintiffs,

V.

FOREVERGREEN INTERNATIONAL, LLC,

Defendant.

Civ. Action No. 4:19-cv-00130

JURY TRIAL DEMANDED

PLAINTIFFS' FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Axxess Global Sciences, LLC (“AGS”), Pruvit Ventures, Inc. (“Pruvit”), and University of South Florida Research Foundation, Inc. (“USF”) (collectively “Plaintiffs”) file this first amended complaint against ForeverGreen International, LLC (“ForeverGreen” or “Defendant”), and in support thereof, state as follows:

I. NATURE OF THE ACTION

1. Plaintiffs bring this action to enjoin the importation, distribution, use, sales and offers to sell by Defendant ForeverGreen of a certain product known as “KetonX” (“Infringing Product”) that infringes or contributes toward the infringement of valid and enforceable U.S. patents owned by USF, which is a direct support organization of the University of South Florida. AGS is the exclusive licensee of such patents and Pruvit is the exclusive sublicensee of such patents. Although Defendant previously had a sublicense under one or more of the patents-in-suit, such sublicense was expressly terminated at least as early as February 2017. Given Defendant’s indisputable and intimate knowledge of the patents-in-suit, Plaintiffs further seek monetary

damages for Defendant's willful infringement.

II. THE PARTIES

2. Plaintiff Axxess Global Sciences, LLC is a limited liability company organized under the laws of the State of Utah with its principal place of business at 2040 East Murray Holladay Road, Holladay, UT 84117.

3. Plaintiff Pruvit Ventures, Inc. is a corporation organized under the laws of the State of Texas with its principal place of business at 901 Sam Rayburn Highway, Melissa, TX 75454.

4. Plaintiff University of South Florida Research Foundation, Inc. is a nonstock, nonprofit Florida corporation pursuant to Chapter 617 of the Florida Statutes, with its principal place of business at 3802 Spectrum Boulevard, Suite 100, Tampa, FL 33612.

5. Defendant ForeverGreen International, LLC is a limited liability company organized under the laws of the State of Utah with its principal place of business at 632 North 2000 West, Suite #101, Lindon, UT 84042.

III. JURISDICTION AND VENUE

6. This is a civil action for patent infringement arising under the United States patent statutes, 35 U.S.C. § 1, *et seq.*

7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

8. Defendant is subject to this Court's personal jurisdiction because it does and has done substantial business in this judicial district, including selling and offering to sell the Infringing Product throughout the United States, and particularly in Texas and in this judicial district. In addition, upon information and belief, Defendant (directly and/or through a distribution network) has or intends to regularly place the Infringing Product in the stream of commerce with

the knowledge and/or understanding that the Infringing Product will be sold in Texas and in the Eastern District. Defendant is subject to the general jurisdiction of this Court because it has regular and systematic contacts with this forum such that the exercise of jurisdiction over it would not offend traditional notions of fair play and substantial justice.

9. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c), as well as under 28 U.S.C. § 1400(b); namely, Defendant has committed acts of infringement in this judicial district and has a regular and established place of business in this judicial district.

IV. THE PATENTS-IN-SUIT

10. On September 22, 2015, the United States Patent and Trademark Office (“USPTO”) duly and legally issued to USF United States Patent No. 9,138,420 (“’420 Patent,” attached as **Exhibit A**), entitled “Compositions and Methods for Producing Elevated and Sustained Ketosis.” The ’420 Patent includes five (5) independent claims and thirty-eight (38) dependent claims.

11. Any required maintenance fees have been paid, and the ’420 Patent has not expired. USF is the owner by assignment of the entire right, title, and interest in the ’420 Patent.

12. On June 13, 2017, the USPTO duly and legally issued to USF United States Patent No. 9,675,577 (“’577 Patent,” attached as **Exhibit B**), entitled “Compositions and Methods for Producing Elevated and Sustained Ketosis.” The ’577 Patent is a continuation of the ’420 Patent. The ’577 Patent includes three (3) independent claims and twenty-three (23) dependent claims.

13. Any required maintenance fees have been paid, and the ’577 Patent has not expired. USF is the owner by assignment of the entire right, title, and interest in the ’577 Patent.

V. FACTS

A. Summary Overview

14. In the past, ForeverGreen was a sublicensee of the ’420 Patent and even attempted to enforce the ’420 Patent through litigation in this Court; however, any and all rights that

ForeverGreen once had to practice the '420 Patent (or any patent in the family) were expressly and unequivocally terminated at least as early as February 2017. Accordingly, ForeverGreen is fully aware that any continued use of the patented technology is unauthorized and constitutes willful infringement. As detailed below, ForeverGreen is currently making and selling a product under the brand "KetonX" that infringes both the '420 Patent and the '577 Patent (a continuation of the '420 Patent). Such infringement is willful.

B. 2013 — AGS Obtains from USF an Exclusive License to the '420 Patent, Including Right to Sublicense

15. AGS is a wholly-owned entity of Axxess Global, LLC ("Axxess Global"). In early 2013, Axxess Global began exploring the possibility of obtaining rights in a technology developed at USF for rapidly inducing a state of ketosis.

16. Ketosis is a metabolic state in which most of the body's energy supply comes from ketone bodies in the blood, in contrast to a state of glycolysis in which blood glucose provides most of the energy. Medical literature supports ketosis as positively influencing those with metabolic syndrome, diabetes, chronic neurodegeneration (Alzheimer's, Parkinson's, dementia, ALS, etc.), traumatic brain injury, epilepsy, and other maladies.

17. On September 4, 2013, USF and Axxess Global executed an "Exclusive License Agreement with Sublicensing Rights" ("2013 USF License") that granted to Axxess Global an exclusive license for USF's then patent-pending technology relating to the use of a nutritional supplement including a medium chain fatty acid ("MCT oil") and a beta-hydroxybutyrate salt ("BHB salt") that would assist in inducing and prolonging a state of ketosis in mammals. This USF patent application subsequently issued as the '420 Patent. The 2013 USF License expressly granted to Axxess Global the right to sublicense. Axxess Global's rights in the 2013 USF License were assigned to Plaintiff AGS, its wholly-owned entity.

C. 2014 — AGS Grants to Pruvit and ForeverGreen a Sublicense to the '420 Patent

18. On December 31, 2014, AGS and Pruvit executed a “Non-Exclusive Sublicense Agreement” (“2014 Pruvit Sublicense”) that granted to Pruvit a non-exclusive sublicense to practice the '420 Patent. In early June of 2015, Pruvit began marketing and offering for sales products branded as “Keto-OS” and “Keto-COS.”

19. On July 7, 2015, AGS and ForeverGreen executed a “Sublicense Agreement re USF Technology” (“2015 FG Sublicense”) that granted to ForeverGreen an exclusive sublicense to practice the '420 Patent in the multi-level marketing channel. However, because AGS had previously executed the 2014 Pruvit Sublicense granting Pruvit non-exclusive rights to the '420 Patent in the multi-level marketing channel, the exclusive license granted under the 2015 FG Sublicense was made expressly “subject to” any rights that Pruvit “may have as a non-exclusive licensee.”

D. 2015-2016 — ForeverGreen Asserts Infringement of '420 Patent

20. In mid-2015, a dispute developed between ForeverGreen and AGS, on the one hand, and Pruvit, on the other. Left with no other choice, on August 24, 2015, Pruvit filed a Complaint in the Eastern District of Texas, Sherman Division (Civil Action No. 4:15-cv-00571-ALM-CAN), in which Pruvit asserted various causes of action against both ForeverGreen and AGS.

21. On October 26, 2015, ForeverGreen filed its Answer, Counterclaims and Third-Party Complaint against Pruvit, in which ForeverGreen asserted “Infringement of U.S. Patent No. 9,138,420 against Pruvit [and others]” as well as various other causes of action. Among other allegations, ForeverGreen expressly stated that “The USF Patent (U.S. Patent No. 9,138,420) is valid, enforceable, and was duly issued by the United States Patent and Trademark Office in full compliance with Title 35, United States Code.”

22. Ultimately, the parties reached an amicable settlement of all claims asserted in the 2015 litigation and jointly moved to dismiss. Accordingly, this Court entered an Order of Dismissal, with prejudice, on April 26, 2016.

23. Pursuant to the negotiated resolution among AGS, ForeverGreen, and Pruvit, each of ForeverGreen and Pruvit was entitled to continue making and selling products within the scope of the '420 Patent.

E. 2017 — AGS Terminates ForeverGreen's Sublicense to '420 Patent

24. On February 27, 2017, AGS provided written notice to AGS that the 2015 FG Sublicense was terminated pursuant to Section 9.6 of the FG Sublicense Agreement, which provides that "Licensor may immediately terminate this Agreement...if royalty payments for any calendar quarter are below \$25,000."

25. On June 7, 2017, subsequent to further discussions and correspondence between AGS and ForeverGreen, AGS provided further written confirmation to ForeverGreen that AGS "has already terminated the [2015 FG Sublicense] because of ForeverGreen's numerous breaches of the agreement, including notably, its utter failure to perform its obligations. Accordingly, ForeverGreen must exit the BHB-based ketogenic market. AGS has no interest in any type of ongoing licensing agreement with ForeverGreen."

26. Upon information and belief, ForeverGreen ceased making and selling any products embodying the '420 Patent in or about June 2017.

F. 2018 — AGS Grants to Pruvit an Exclusive Sublicense to '420 Patent and '577 Patent

27. On May 1, 2018, AGS and Pruvit executed a "World-Wide Exclusive Sublicense Agreement – D'Agostino Technology" ("2018 Pruvit Exclusive Sublicense") that granted to Pruvit an exclusive sublicense to practice the '420 Patent and the '577 Patent in the multi-level marketing channel.

28. Currently, Pruvit is the sole and exclusive sublicensee of the '420 Patent and the '577 Patent, and any rights that ForeverGreen may have had to practice the '420 Patent and/or the '577 Patent have been expressly and unequivocally terminated.

G. The Infringing Product – “KetonX”

29. The Infringing Product is manufactured and sold by ForeverGreen under the brand “KetonX.”

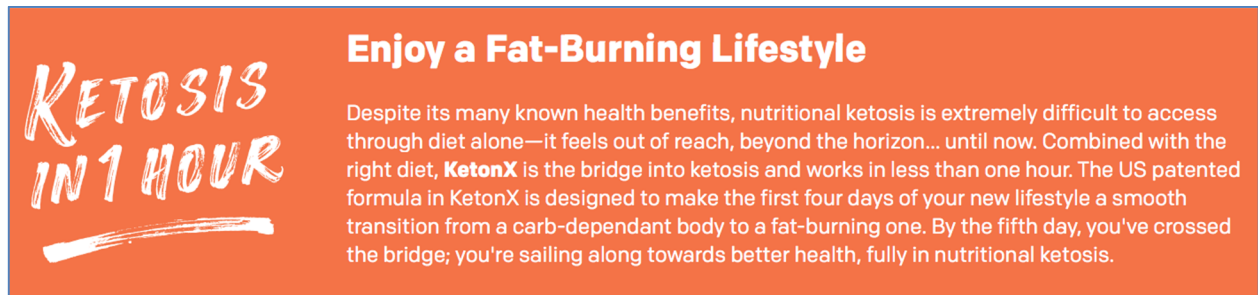
30. According to the KetonX product sheet in the ForeverGreen Catalog (available online at <<http://forevergreen.org/productcatalog/KetonX-CatalogPage-EN.pdf>>), the Infringing Product is a “Proprietary Blend” of DL-3 Hydroxybutyric Acid, Medium Chain Triglyceride, and Green Tea Extracts. Following are the “Supplement Facts” accompanying the Infringing Product:

Supplement Facts	
4 servings per container	
Serving size	1 Packet (24g)
Amount per Serving	% Daily Value*
Calories 70	
Calories from Fat 40	
Total Fat 5g	6%
Saturated Fat 5g	25%
Total Carbohydrates 7g	3%
Dietary Fiber 1g	4%
Sugars 2g	
Protein 1g	
Calcium 448mg	34%
Magnesium 37mg	9%
Sodium 330mg	14%
Potassium 682mg	15%
Proprietary Blend 14.5g	
DL-3 Hydroxybutyric Acid (as calcium, potassium, sodium, and magnesium salts)	†
Medium Chain Triglyceride (MCT oil, digestion resistant maltodextrin)	†
Green Tea Extracts (75% catechin extract, 50% caffeine extract)	†
Other Ingredients: Erythritol, fructose, L-Lysine, L-Leucine, citric acid, inulin, natural orange flavor (maltodextrin, rice starch, natural flavors, modified food starch), silicon dioxide, coconut creamer (coconut oil, corn syrup solids, sodium caseinate, mono & diglycerides, dipotassium phosphate and sodium silico aluminat), stevia extract, malic acid, natural orange cream flavor, Raspberry flavor blend (natural raspberry flavor, artificial vanilla flavor, tri-calcium citrate), lecithin, natural beetroot color, riboflavin (for color), sunflower powder, non fat dry milk.	
* % Daily Values (%DV) are based on a 2,000 calorie diet. † Daily Value not established.	

31. ForeverGreen claims that “[i]ts patented technology contains exogenous ketones Beta-hydroxybutyrate (or BHB salts), and MCT oils (multiple-chain triglycerides).” ForeverGreen explains that “Nutritional Ketosis is a metabolic state where your body burns fat for energy instead of relying on carbs and sugar. ... Some of the amazing results of this process are increased mental function and clarity, reduced hunger and cravings, improved mood, better sleep and of course, weight loss.” ForeverGreen further explains that “[t]he US patented formula in KetonX is designed to make the first four days of your new lifestyle a smooth transition from a

carb-dependant [sic] body to a fat-burning one. By the fifth day, you've crossed the bridge ...”

Following are screenshots from the KetonX product sheet:



Enjoy a Fat-Burning Lifestyle

Despite its many known health benefits, nutritional ketosis is extremely difficult to access through diet alone—it feels out of reach, beyond the horizon... until now. Combined with the right diet, **KetonX** is the bridge into ketosis and works in less than one hour. The US patented formula in KetonX is designed to make the first four days of your new lifestyle a smooth transition from a carb-dependant body to a fat-burning one. By the fifth day, you've crossed the bridge; you're sailing along towards better health, fully in nutritional ketosis.

KetonX features a specific blend of natural ingredients that allow the body to begin converting to a state of nutritional ketosis within hours, not days! Its patented technology contains exogenous ketones Beta-hydroxybutyrate (or BHB salts), and MCT oils (multiple-chain triglycerides). Both are natural ingredients that help the body become fat adapted and enter ketosis more quickly. By using KetonX as a bridge the first four days of your new lifestyle, you can transition into ketosis smoothly, avoiding the effects of the keto flu. By the fifth day, you're fully in nutritional ketosis. KetonX is also great to have on a shelf for those times when you might slip out of ketosis— simply use another bridge to get back on board. Once you're sailing in ketosis, you can completely enjoy all the benefits of a fat-burning, keto lifestyle.

32. Plaintiffs AGS and Pruvit recently obtained a sample of the Infringing Product and commissioned lab testing regarding the composition thereof. Among other components, the results included the following:

- 5.0174 g MCT per testing— more specifically, testing indicated 0.0044 g Caproic Acid + 2.87 g Caprylic Acid + 2.04 g Capric Acid + 0.103 g Lauric Acid
- 6.25 g BHB per testing — more specifically, KetonX product sheet specifies that BHB is provided in the form of calcium, potassium, sodium and magnesium salts

The complete Certificate of Analysis setting forth the Analytical Testing Results for the Infringing Product is attached as **Exhibit C**.

33. By way of example but not limitation, independent claim 1 of the '420 Patent reads as follows:

A composition, comprising:

at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams; and

at least one beta-hydroxybutyrate compound in an amount between about 2 grams and about 50 grams, wherein the at least one beta-hydroxybutyrate compound is comprised of a beta-hydroxybutyrate salt.

34. Based on the testing results included in the Certificate of Analysis in **Exhibit C**, as well as the product sheet and Supplement Facts accompanying the KetonX product made and sold by ForeverGreen, the Infringing Product satisfies each element of at least independent claim 1 of the '420 Patent.

35. By way of example but not limitation, independent claim 1 of the '577 Patent reads as follows:

A method of promoting or sustaining ketosis in a mammal, comprising:

administering at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams per day for at least one day; and

administering at least one beta-hydroxybutyrate compound, where the at least one beta-hydroxybutyrate compound is beta-hydroxybutyrate monomer salt in an amount between about 2 grams and about 50 grams per day for at least one day.

36. Based on the testing results included in the Certificate of Analysis in **Exhibit C**, as well as the product sheet and Supplement Facts accompanying the KetonX product made and sold by ForeverGreen, the Infringing Product satisfies each element of at least independent claim 1 of the '577 Patent.

VI. COUNT I
INFRINGEMENT OF THE '420 PATENT

37. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 36 of this First Amended Complaint as if fully set forth herein.

38. Plaintiffs are the owner (USF), exclusive licensee (AGS), and exclusive sublicensee (Pruvit), respectively, of the entire right, title, and interest in the '420 Patent.

39. Defendant has and continues to use, import, distribute, offer to sell, and/or sell in the United States the Infringing Product that infringes the '420 Patent. Specifically, the Infringing Product infringes at least claims 1-3, 5-6, 12-13, 29, 32-34, 36, and 39-41 of the '420 Patent literally and/or under the doctrine of equivalents. The Infringing Product infringes claims 1-3, 5-6, 12-13, 29, 32-34, 36, and 39-41 of the '420 Patent at least because the Infringing Product includes each and every limitation of claims 1-3, 5-6, 12-13, 29, 32-34, 36, and 39-41.

40. Defendant was aware of the '420 Patent.

41. Defendant infringes and will continue to infringe claims 1-3, 5-6, 12-13, 29, 32-34, 36, and 39-41 of the '420 Patent by using, importing, distributing, offering to sell, and/or selling within the United States the Infringing Product.

42. Defendant's infringement of the '420 Patent is willful.

43. Plaintiffs have been, and will continue to be, damaged and irreparably harmed by Defendant's infringement, which will continue unless Defendant is enjoined by this Court.

VII. COUNT II
INFRINGEMENT OF THE '577 PATENT

44. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 43 of this First Amended Complaint as if fully set forth herein.

45. Plaintiffs are the owner (USF), exclusive licensee (AGS), and exclusive sublicensee (Pruvit), respectively, of the entire right, title, and interest in the '577 Patent.

46. Defendant has and continues to use, import, distribute, offer to sell, and/or sell in the United States the Infringing Product that infringes the '577 Patent. Specifically, the Infringing Product infringes at least claims 1-4, 7-10, and 13-17 of the '577 Patent literally and/or under the doctrine of equivalents. The Infringing Product infringes claims 1-4, 7-10, and 13-17 of the '577 Patent at least because the Infringing Product includes each and every limitation of claims 1-4, 7-10, and 13-17.

47. Defendant was aware of the '577 Patent.

48. Defendant infringes and will continue to infringe the claims of the '577 Patent by using, importing, distributing, offering to sell, and/or selling within the United States the Infringing Product.

49. Defendant's infringement of the '577 Patent is willful.

50. Plaintiffs have been, and will continue to be, damaged and irreparably harmed by Defendant's infringement, which will continue unless Defendant is enjoined by this Court.

VIII. REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief against Defendant:

A. A judgment that the '420 Patent and the '577 Patent are each duly and legally issued, valid, and enforceable;

B. A judgment holding Defendant liable for infringement of the '420 Patent and the '577 Patent;

C. A temporary restraining order, preliminary injunction, and permanent injunction against Defendant, its officers, agents, servants, employees, attorneys, parent and subsidiary corporations, assigns and successors in interest, and those persons in active concert or participation with them, enjoining them from continued acts of infringement of the '420 Patent and/or the '577 Patent, including without limitation, an injunction against offers for sale and future sales of the Infringing Product and colorable imitations thereof;

D. An accounting for damages and an award of compensatory damages resulting from Defendant's infringement of the '420 Patent and/or the '577 Patent, together with pre-judgment and post-judgment interest;

E. A judgment holding that Defendant's infringement of the '420 Patent and/or the '577 Patent is willful and a trebling of damages pursuant to 35 U.S.C. § 284;

F. A judgment holding that this action is an exceptional case and an award to Plaintiffs for their attorney's fees and costs pursuant to 35 U.S.C. § 285 and other authority;

G. A judgment that Plaintiffs be awarded their costs incurred herein; and

H. Such other relief as the Court deems just and equitable.

IX. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs hereby demand trial by jury.

Dated: June 14, 2019

Respectfully submitted,

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FOUNDATION, INC.

CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2019, Plaintiffs' First Amended Complaint for Patent Infringement was electronically filed and served on all attorneys of record.

/s/ Kelly J. Kubasta

Kelly J. Kubasta